



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10286, CMS-10440 and CMS-10507]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. Electronically. You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. By regular mail. You may mail written comments to the following address:

CMS, Office of Strategic Operations and Regulatory Affairs

Division of Regulations Development

Attention: Document Identifier/OMB Control Number _____

Room C4-26-05

7500 Security Boulevard

Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web Site address at Web Site address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>

2. E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.

3. Call the Reports Clearance Office at (410) 786-1326.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786-1326.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see ADDRESSES).

CMS-10286 Notice of Research Exception under the Genetic Information Nondiscrimination Act

CMS-10440 Data Collection to Support Eligibility Determinations for Insurance Affordability

Programs and Enrollment through Affordable Insurance Exchanges, Medicaid and

Children's Health Insurance Program Agencies (CMS-10440)

CMS-10507 State-based Exchange Annual Report Tool (SMART)

Under the PRA (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Notice of Research Exception under the Genetic Information Nondiscrimination Act; Use: Under the Genetic Information Nondiscrimination Act of 2008 (GINA), a plan or issuer may request (but not require) a genetic test in connection with certain research activities so long as such activities comply with specific requirements, including: (i) The research complies with 45 CFR part 46 or equivalent federal regulations and applicable State or local law or regulations for the protection of human subjects in research; (ii) the request for the participant or beneficiary (or in the case of a minor child, the legal guardian of such beneficiary) is made in

writing and clearly indicates that compliance with the request is voluntary and that non-compliance will have no effect on eligibility for benefits or premium or contribution amounts; and (iii) no genetic information collected or acquired will be used for underwriting purposes. The Secretary of Labor or the Secretary of Health and Human Services is required to be notified if a group health plan or health insurance issuer intends to claim the research exception permitted under Title I of GINA. Nonfederal governmental group health plans and issuers solely in the individual health insurance market or Medigap market will be required to file with the Centers for Medicare & Medicaid Services (CMS). The Notice of Research Exception under the Genetic Information Nondiscrimination Act is a model notice that can be completed by group health plans and health insurance issuers and filed with either the Department of Labor or CMS to comply with the notification requirement. Form Number: CMS-10286 (OMB control number 0938-1077); Frequency: Occasionally; Affected Public: State, Local or Tribal Governments; Private Sector; Number of Respondents: 2; Number of Responses: 2; Total Annual Hours: 0.5. (For policy questions regarding this collection contact Usree Bandyopadhyay at 410-786-6650.)

2. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Data Collection to Support Eligibility Determinations for Insurance Affordability Programs and Enrollment through Affordable Insurance Exchanges, Medicaid and Children's Health Insurance Program Agencies; Use: Information collected by the Marketplace, Medicaid or CHIP agency will be used to determine eligibility for coverage through the Marketplace and insurance affordability programs (i.e., Medicaid, CHIP, and advance payment of the premium tax credits), and assist consumers in enrolling in a QHP if eligible. Applicants include anyone who may be eligible for coverage through any of these programs.

The Marketplace verifies the information provided on the application, communicates with the

applicant or his/her authorized representative and subsequently provides the information to the health plan selected by the applicant so that it can enroll him/her in a QHP. The Marketplace also uses the information provided in support of its ongoing operations, including activities such as verifying continued eligibility for all programs, processing appeals, reporting on and managing the insurance affordability programs for eligible individuals, performing oversight and quality control activities, combatting fraud, and responding to any concerns about the security or confidentiality of the information. Form Number: CMS-10440 (OMB control number: 0938-1191); Frequency: Annually; Affected Public: Private Sector (Business or other for-profits, Not-for-Profit Institutions); Number of Respondents: 4,662,000; Total Annual Responses: 4,662,000; Total Annual Hours: 946,386. (For policy questions regarding this collection contact Anne Pesto at 410-786-3492.)

3. Type of Information Collection Request: Revision of a currently approved collection; Title of Information Collection: State-based Exchange Annual Report Tool (SMART); Use: The annual report is the primary vehicle to insure comprehensive compliance with all reporting requirements contained in the Affordable Care Act (ACA). It is specifically called for in Section 1313(a)(1) of the Act which requires an State Based Exchange (SBEs) (including an Exchange using the Federal Platform) to keep an accurate accounting of all activities, receipts, and expenditures, and to submit a report annually to the Secretary concerning such accounting.

CMS and other Federal agencies use the information collected from the SMART to determine if a state is maintaining a compliant, operational Exchange. It also provides a mechanism to collect innovative approaches to meeting challenges encountered by the SBEs during the preceding year, as well as to provide information to CMS regarding potential changes in priorities and approaches for the upcoming year. Form Number: CMS-10507 (OMB control number: 0938-1244); Frequency: Annually; Affected Public: State, Local, or Tribal governments; Number of

Respondents: 17; Total Annual Responses: 17; Total Annual Hours: 3,415. (For policy questions regarding this collection contact Christy Woods at 301-492-5140.)

Dated: November 20, 2018.

William N. Parham, III,

Director, Paperwork Reduction Staff,

Office of Strategic Operations and Regulatory Affairs.

BILLING CODE 4120-01-U-P

[FR Doc. 2018-25700 Filed: 11/23/2018 8:45 am; Publication Date: 11/26/2018]